REMARKS

Claims 1-8 are pending in this application. Claims 1, 2 and 5-8 are withdrawn based on an election to a restriction requirement. Claims 3 and 4 stand rejected.

Sequence Rules

The Examiner requires that the Applicants include sequence identifiers for the sequences listed on page 23, lines 9-11. The Applicants herein amend the specification to include sequence identifiers for these sequences. In addition, the Applicants provide an amended Sequence Listing herewith including these three sequences provided in the specification.

Specification

The Examiner suggests that the title of the application be amended to "VANILREP4 POLYPEPTIDES." The Applicants herein amend the title as the Examiner suggests. The Examiner also suggests that hyperlinks be removed from the specification and the typographical errors be corrected by amendment. The Applicants herein amend the specification to remove all browser-executable code as well as correct the typographical errors pointed out by the Examiner in the Office Action.

35 U.S.C. § 101 and 35 U.S.C. § 112

Claims 3 and 4 stand rejected under 35 U.S.C. § 101 because the Examiner alleges that the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. Specifically, the Examiner concedes that the specification discloses that mRNA encoding SEQ ID NO:2 is expressed is the kidney and peripheral tissue as well as in the CNS. The Examiner also concedes that the specification discloses that HEK293 cells transiently expressing hVR4 were activated by PMA and 4αPDD. However, the Examiner alleges that the specification does not teach any expression data or functional characteristics of the VANILREP4 polypeptide set forth in SEQ DI NO:2. The Examiner alleges that without any biological data or link to disease the application is insufficient to support utility. The Examiner concedes that it is credible that SEQ ID NO:2 is a member of the vanilloid family; however, the Examiner alleges that its identification as an ion channel is not sufficient to establish utility. To support this allegation the Examiner alleges that vanilloid receptors are activated by a diverse range of stimuli, and he cites Gunthorpe, *et al.* (2002) Trends in Pharmacological Science. Finally, the Examiner asserts that the present case leaves it to the practitioner to discover the identity of the disease or disorder in which the claimed VANILREP4 protein of the instant invention is associated.

The Applicants respectfully traverse this rejection. First, the Applicants respectfully point out that the application lists several diseases for which the claimed polypeptides have substantial and credible utility; see for instance, page 1, line 32 through page 2, line 6. Second, as the Examiner concedes, the application directs the skilled artisan to certain tissue types that contain mRNA encoding SEQ ID NO:2. Third, the application also provides, as the Examiner concedes, methods for detecting agonist and antagonists to VANILREP4 polypeptides as well as two examples of an agonists to this receptor. Thus, the application provides sufficient disclosure to meet the requirements for specific, substantial and credible utility. The Applicants respectfully submit that the disclosure provided in the present application is sufficient to establish utility regardless of any observation that vanilloid receptors may by activated by different stimuli, as this application shows two specific agonists for the vanilloid receptor claimed.

In view of the above-referenced disclosure of the biological importance of human VANILREP4 polypeptides disclosed in the instant application, the Applicants submit that the instantly claimed invention has asserted specific and substantial utilities. "The PTO has the initial burden of challenging a patent applicant's presumptively correct assertion of utility." *In re Swartz*, 56 U.S.P.Q.2d 1703, 1704 (Fed. Cir. 2000) (*citing In re Brana*, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995)). However, if the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility, the burden shifts to the applicant to submit evidence sufficient to convince such a person of the invention's asserted utility. *Id.* The Applicant respectfully submits that the Examiner has not fulfilled his burden under the law to challenge the Applicant's presumptively correct asserted utility. Through the above-referenced disease associations disclosed in the instant application for the claimed polypeptides, the Applicants submit that they have established a legally sufficient utility for the instantly claimed polypeptides. In view of the ample evidence provided above, the Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 3 and 4 under 35 U.S.C. § 101 and 112.

Respectfully submitted,

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